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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/087,136 05/28/98 HORVITZ

H 01997/202002

HM22/0606

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EXAMINER

CANELLA, K

ART UNIT

PAPER NUMBER

1642

DATE MAILED:

06/06/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.  
09/087,136

Applicant(s)  
Horovitz et al

Examiner  
Karen Canella

Art Unit  
1642



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 months MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_\_
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1, 4-7, 10-18, and 25 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 4-7, 10-18, and 25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirements.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_
- 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: \_\_\_\_\_

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***Response to Amendment***

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.
2. Claims 2, 3, 8, 9, 19-24 and 26-33 have been canceled. Claims 1, 7, 10, 16, 18 and 25 have been amended. Claims 1, 4-7, 10-18 and 25 are pending and under consideration.

***Claim Rejections Maintained***

3. The rejection of claims 1, 4-7, 10-18 and 25 under 35 U.S.C. 101, because the claimed invention is not supported by a specific and substantial utility, is maintained for reasons of record. Applicant argues that the specification teaches that synMuv polypeptides act to negatively regulate vulval induction and may be used to modulate cell proliferation. The examiner maintains that the utility remains hypothetical as the specification teaches that the synMuv polypeptides negatively regulate vulval induction in *C elegans*. There are no teachings in the specification to provide any objective evidence that the synMuv polypeptides can modulate cell proliferation in human cells or any mammalian cells, nor is there any objective evidence that these peptides could be used as potential anti-neoplastic or anti-tumor agents.
4. The rejection of claims 1, 4-7, 10-18 and 25 under 35 U.S.C. 112, first paragraph, is maintained for reasons of record. Specifically, since the claimed invention is not supported by a well established utility for the reasons set forth in the rejection under 35 USC 101 above, one skilled in the art clearly would not know how to use the claimed invention.
5. For reasons of record, it is maintained that in the event that Applicants might be able to overcome the 35 USC 101 rejection and 35 U.S.C. 112 above, the specification would still be enabling only for claims limited to polynucleotides that encode SEQ ID NO:1. Applicant argues that the claim limitations requiring the claimed variant polypeptides to have the ability to alter cell

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proliferation allows one of skill in the art to identify such proteins. This is not found persuasive. Firstly, the specification has not enabled claims drawn to the polypeptide of SEQ ID NO:1 for the reasons state in the office action of Paper No. 16. Secondly, the specification has not taught that it is possible to alter the amino acid sequence of SEQ ID NO:1 and retain the same claimed activity of the synMuv polypeptide, nor has the specification given any guidance on the which amino acids in the synMuv polypeptide will tolerate substitutions.

6. The rejection claims 1, 5, 15 and 25 under 35 U.S.C. 102(a) as being anticipated by Lu and Horvitz (June 1996 meeting) is maintained. The rejection of claims 1, 3, and 5 under 35 U.S.C. 102(a) as being anticipated by Ceol and Horvitz (June 1996 meeting) is maintained. Rejection of claims 1,3,5,11,14-16 under 35 U.S.C. 102(a) as being anticipated by Lu and Horvitz (May 1997 meeting) is maintained. The rejection of claim 25 under 35 U.S.C. 102(a) as being anticipated by Ceol and Horvitz (May 1997 meeting) is maintained. Applicant argues that the examiner is misinterpreting the definition of inventive entity in that previous publications with authorships consisting of less than all of the instant inventors is not to be considered a different inventive entity. This is not found persuasive. The instant inventive entity consists of Horvitz, Ceol and Lu. Previous publications by Horvitz and Ceol, and Horvitz and Lu constitute different inventive entities as Horvitz + Ceol + Lu does not equal Horvitz + Ceol nor does it equal Horvitz + Lu.

***Claim Rejections Withdrawn***

7. The rejection of claims 1, 4-6, 10-18 and 25 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, is withdrawn.

8. The rejection of claims 1, 5, 7 and 15 under 35 U.S.C. 102(b) as being anticipated by Accession number U00047 is withdrawn.

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***Conclusion***

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Canella whose telephone number is (703) 308-8362. The examiner can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.



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Karen A. Canella, Ph.D.  
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June 2, 2001